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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,070	07/10/2006	Barry J. Sender	1952023-00001	5527
45200	7590	10/28/2010	EXAMINER	
K&L Gates LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319			NGUYEN, TRANG T	
			ART UNIT	PAPER NUMBER
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			10/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/597,070	Applicant(s) SENDER ET AL.	
	Examiner TRANG NGUYEN	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8-10,12,13,18,20-22,24-28,31,34-36 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8-10,12,13,18,20-22,24-28,31,34-36 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. The following is a Final office action in response to the communications received on August 13, 2010.
2. Claims 1, 2, 5, 10, 12, 13, 22, 24, 27, 31, 36 and 39 have been amended.
3. Claims 3, 4, 6, 7, 11, 14 - 17, 19, 23, 29, 30, 32, 33, 37 and 38 have been cancelled.
4. Claims 1, 2, 5, 8-10, 12, 13, 18, 20-22, 24-28, 31, 34-36 and 39 are currently pending and have been examined.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 5, 12, 31 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. A claim can not refer to a figure within the body of a claim.
Appropriate correction is requested.
7. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitations: "The disease management system according to claim 16 ..." There is insufficient antecedent basis for this limitation in the claim. For the purpose of this examination, (since claim 16 has been cancelled), the Examiner will assume the claim is written as such: "The disease management system according to claim 12, wherein ..."

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 39 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 39 is directed to a method. However, the recited steps of the method are held to be non-statutory subject matter because the recited steps of the method are (1) not tied to another statutory class (such as a particular apparatus) or (2) not transforming the underlying subject matter (such as an article or materials) to a different state or thing.

10. Claims 1, 2, 5, 8-10, 12-13, 18, 20-22, 24-26 and 31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

A claim directed to or including within its scope a human being (i.e. data interpretation means and therapeutic dispensing means) will not be considered to be patentable subject matter under 35 U.S.C. 101. Appropriate correction is required.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1, 2, 5, 8-10, 12, 13, 18, 20-22, 24, 25, 27, 28, 31, 34-36 and 39 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Barry (US 6188988 B1) in view of Linberg et al. (US 20010039504 A1A1).

Regarding claims 1, 12, 24 and 39:

Barry as shown discloses the following limitations:

A human immunodeficiency virus (HIV) related disease management system comprising:

patient data comprising at least one type of data selected from the, group consisting of physical examination data, laboratory data, and patient history data (See at least Fig. 4, column 3, lines 40-43; column 4, lines 59-67); data interpretation means (See at least column 8, lines 1-55; column 10, lines 23-34); and wherein said data collection means is used to obtain disease state information from a patient having HIV related disease wherein said patient is located remotely relative to said data interpretation means and said therapeutic dispensing means and wherein said data interpretation means is located on a computer-readable medium and provides diagnostic, prognostic and therapeutic information useful for the management of said HIV related disease of said patient (See at least Fig. 3; abstract; column 4, lines 43-50; column 6, lines 62-63).

Barry may or may not disclose: *therapeutic dispensing means*. However, Linberg discloses gathering and transferring data into a data management center where the data may be analyzed, with relevant therapy/clinical care dispensed accordingly (paragraph 0012).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Barry so as to have added therapeutic dispensing means, in accordance with the teaching of Linberg, in order to dispense the

relevant therapy/clinical care to the patient, to have improved the efficiency of the system, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Regarding claims 2, 13 and 28 Barry further discloses:

The disease management system of claim 1 wherein said data is collected by a non-physician healthcare worker or a laboratory (See at least column 7, lines 61-67).

Regarding claims 5 and 31:

Barry may or may not disclose the following limitation. However, Linberg discloses:

The disease management system of claim 1 wherein said data interpretation means comprises the algorithm of Figure 4 (See at least Fig. 1; paragraph 0175).

Furthermore, it is old and well known in the art to use flowchart such as the one in Fig. 4 to show step-by-step progression through a procedure or system, especially using connecting lines and a set of conventional symbols within the diagram.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this data and analysis to the system of Barry because the individual elements are old and well known and the combination would have yielded predictable results.

Regarding claims 8, 20 and 34:

Barry may or may not disclose the following limitation. However, Linberg discloses:

The disease management system of claim 1 wherein said therapeutic dispensing means comprises a pharmacy (See at least paragraph 0109).

Furthermore, it is old and well known in the art that one function of pharmacy is to dispense medicine. It would have been obvious to one of ordinary skill in the art at the

time of the invention to add this data and analysis to the system of Barry because the individual elements are old and well known and the combination would have yielded predictable results.

Regarding claim 18 Barry further discloses:

The disease management system according to claim 16 wherein said algorithm is stored on a computer-readable medium (See at least column 4, lines 43-50).

Regarding claim 27:

Barry as shown discloses the following limitations:

A method for managing HIV related disease in a patient located remotely relative to data interpretation means and therapeutic dispensing means comprising:

collecting a first set of data from said remotely located patient having an HIV related disease (See at least Fig. 3, 4, abstract; column 3, lines 40-43; column 4, lines 59-67; column 5, lines 1-24; column 7, lines 61-67; column 8, lines 1-55);

interpreting said first set of data in order to determine an appropriate first therapeutic regimen for said remotely located patient (See at least column 8, lines 1-55);

collecting at least one second set of data from said remotely located patient;

interpreting said at least one second set of data in order to determine the appropriateness of continuing or stopping said first therapeutic regimen or altering said first therapeutic regimen for said remotely located patient; and

wherein said first and at least one second interpreting step comprises an algorithm located on a computer-readable medium that provides diagnostic,

prognostic and therapeutic information useful for the management of said HIV related disease of said patient (See at least column 4, lines 43-50; column 8, lines 1-55; column 10, lines 23-34);

dispensing said first therapeutic regimen to said remotely located patient;

Barry may or may not disclose: *therapeutic dispensing means*. However, Linberg discloses gathering and transferring data into a data management center where the data may be analyzed, with relevant therapy/clinical care dispensed accordingly (paragraph 0012).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Barry so as to have added therapeutic dispensing means, in accordance with the teaching of Linberg, in order to dispense the relevant therapy/clinical care to the patient, to have improved the efficiency of the system, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Regarding claims 9, 21 and 35 Barry further discloses:

The disease management system of claim 1 wherein said computer-readable medium is a selected from the group consisting of hard drives, floppy disks, CD-ROMs, zip drives and flash drives (See at least column 4, lines 16-29).

Regarding claim 25 Barry further discloses:

The disease management system of claim 24 wherein said data comprises a patient history and CD4 levels (See at least column 4, lines 59-67; column 5, lines 1-9; column 13, lines 39-52).

Regarding claims 10, 22 and 36 Barry further discloses:

The disease management system of claim 1 wherein said disease is HIV related disease or acquired immune deficiency syndrome (AIDS) (See at least column 6, lines 62-63).

14. Claim 26 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Barry (US 6188988 B1) in view of Linberg et al. (US 20010039504 A1A1) and further in view of Sperber (US 20040197770 A1).

Barry/Linberg may or may not disclose the following limitation. However, Sperber discloses:

Regarding claim 26:

The disease management system of claim 24 wherein the therapy comprises High Activity Anti-Retroviral Therapy (HAART) (See at least paragraphs 0010, 0020, 0290).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Barry/Linberg so as to have included HAART as the therapy for the disease, in accordance with the teaching of Sperber, in order to include available therapeutic treatments (such as HAART,...) for HIV or AIDS related disease within the system, to have improved the efficiency of the system, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Response to Arguments

15. Applicant's arguments filed June 29, 2010 with respect to claims 1, 2, 5, 8-10, 12, 13, 18, 20-22, 24-28, 31, 34-36 and 39 have been considered but are moot in view of the new ground(s) of rejection.
16. Applicant has not amended Claims 1, 2, 5, 8-10, 12-13, 18, 20-22, 24-26, 31 and 39 to correct the deficiencies stated by the Examiner previously, that is, that they are directed to non-statutory subject matter. As such, the 35 U.S.C. §101 rejection as set forth in the previous office action, is maintained, and made FINAL.
17. Applicant has not amended Claims 12 and 39 to correct the deficiencies stated by the Examiner previously, that is, they fails to point out what is included or excluded by the claim language. As such, the 35 U.S.C. §112 rejection as set forth in the previous office action, is maintained, and made FINAL.
18. Applicant has cancelled claim 38 with respect to the indefiniteness rejection presented in the previous office action. Applicant's amendment is sufficient to overcome the 35 U.S.C. §112 second paragraph rejection as set forth in the previous office action.

As stated in the applicant's response: Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not

for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). MPEP §2173.05(s)

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be

directed to **TRANG NGUYEN** whose telephone number is **(571) 270-5483**. The Examiner can normally be reached on Monday-Thursday 7:00AM - 5:30PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

/T. N./
October 20, 2010
Examiner, Art Unit 3686

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686